



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,411	10/12/2001	Amy B. Reed	03768/09633	1102

7590 01/30/2003

Neil C. Jones
Nelson Mullins Riley & Scarborough
Keenan Building, Third Floor
1330 Lady Street
Columbia, SC 29201

EXAMINER

VO, HAI

ART UNIT	PAPER NUMBER
----------	--------------

1771

DATE MAILED: 01/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/976,411	REED ET AL.	
	Examiner	Art Unit	
	Hai Vo	1771	

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> | 6) <input type="checkbox"/> Other: _____ |

Claim Objections

1. Claims 14-20 are objected to because of the following informalities: the phrase "BFE" needs to be spelled out. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-4, 7, and 14-17 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Isaac et al (US 5,576,364).

The examiner interprets that any web of cellulose fibers saturated or impregnated with a latex composition which is a combination of a natural or synthetic polymer

with a polymer emulsion having a glass transition temperature of -20°C or less would read on the claimed subject matter. Issac teaches a fibrous web being saturated with a latex composition which is a blend of a water dispersible polymer and an elastomeric latex emulsion (column 2, lines 46-59). Since Issac is using the same polyacrylate to form a latex emulsion as Applicants, it is the examiner's position that the glass transition temperature would be inherently present. Since the article of Issac is made of the same material as the medical packaging substrate of the present invention and meets the recited structure set out in the claims, it is the examiner's position that the Gurley Hill porosity and the percent bacterial filtration efficiency (BFE) would be inherently present. Note In re Best 195 USPQ at 433, footnote 4 (CCPA 1977) as to the providing of this rejection under 35 USC 103 in addition to the rejection made under 35 USC 102. It seems from the claim, if one meets the structure recited, the properties must be met or Applicant's claim is incomplete (Note discussion found in Ex parte Slob, 157 USPQ 172). In addition, the examiner wishes to point out that as the USPTO is unequipped to perform the necessary experimentation, the burden of showing the Gurley Hill porosity and the %BFE of the Issac article outside the instantly claimed range is shifted to Applicants.

5. Claims 1-4, and 7-17 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bouchette (US 4,692,374). The examiner interprets that any web of cellulose fibers saturated or impregnated with a latex composition which is a combination of two polymer emulsions wherein one polymer emulsion has a glass transition temperature of -20°C or less would read on

the claimed subject matter. Bouchette teaches a fibrous web being saturated with a latex composition which is a blend of two latex emulsions (column 4, lines 30-43). Since Bouchette is using the same polyacrylate to form a latex emulsion as Applicants, it is the examiner's position that the glass transition temperature would be inherently present. Since the article of Bouchette is made of the same material as the medical packaging substrate of the present invention and meets the recited structure set out in the claims, it is the examiner's position that the Gurley Hill porosity and the percent bacterial filtration efficiency (BFE) would be inherently present. Note In re Best 195 USPQ at 433, footnote 4 (CCPA 1977) as to the providing of this rejection under 35 USC 103 in addition to the rejection made under 35 USC 102. It seems from the claim, if one meets the structure recited, the properties must be met or Applicant's claim is incomplete (Note discussion found in Ex parte Slob, 157 USPQ 172). In addition, the examiner wishes to point out that as the USPTO is unequipped to perform the necessary experimentation, the burden of showing the Gurley Hill porosity and the %BFE of the Bouchette article outside the instantly claimed range is shifted to Applicants.

6. Claims 1-20 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Weber et al (US 5,191,734). The examiner interprets that any web of cellulose fibers saturated or impregnated with a latex composition which is a combination of two polymer emulsions wherein one polymer emulsion has a glass transition temperature of -20°C or less would read on the claimed subject matter. Weber teaches a fibrous web being saturated

with a latex composition which is a combination of solution polymer, synthetic polymer, and natural polymer (column 4, lines 31-34, and table II). The latex is about 16 to 80 dry parts per 100 parts fibers by weight (column 5, line 29). Since Weber is using the same polymer emulsions as Applicants, it is the examiner's position that the glass transition temperature would be inherently present. Since the article of Weber is made of the same material as the medical packaging substrate of the present invention and meets the recited structure set out in the claims, it is the examiner's position that the Gurley Hill porosity and the percent bacterial filtration efficiency (BFE) would be inherently present. Note In re Best 195 USPQ at 433, footnote 4 (CCPA 1977) as to the providing of this rejection under 35 USC 103 in addition to the rejection made under 35 USC 102. It seems from the claim, if one meets the structure recited, the properties must be met or Applicant's claim is incomplete (Note discussion found in Ex parte Slob, 157 USPQ 172). In addition, the examiner wishes to point out that as the USPTO is unequipped to perform the necessary experimentation, the burden of showing the Gurley Hill porosity and the %BFE of the Weber article outside the instantly claimed range is shifted to Applicants.

7. Claims 1-4, and 7-13 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Brown Reed et al (US 6,156,677). The examiner interprets that any web of cellulose fibers saturated or impregnated with a latex composition which is a combination of two polymer emulsions wherein one polymer emulsion has a glass transition temperature of –

20°C or less would read on the claimed subject matter. Brown Reed teaches a fibrous web being saturated with a latex composition which is a combination of a poly(vinylidene chloride)-acrylate and a carnauba wax emulsion (abstract and column 6, lines 1-6). Since Brown Reed is using the same polymer emulsions as Applicants, it is the examiner's position that the glass transition temperature would be inherently present. Since the article of Brown Reed is made of the same material as the medical packaging substrate of the present invention and meets the recited structure set out in the claims, it is the examiner's position that the percent bacterial filtration efficiency (BFE) would be inherently present. Note In re Best 195 USPQ at 433, footnote 4 (CCPA 1977) as to the providing of this rejection under 35 USC 103 in addition to the rejection made under 35 USC 102. It seems from the claim, if one meets the structure recited, the properties must be met or Applicant's claim is incomplete (Note discussion found in Ex parte Slob, 157 USPQ 172). In addition, the examiner wishes to point out that as the USPTO is unequipped to perform the necessary experimentation, the burden of showing the %BFE of the Brown Reed article outside the instantly claimed range is shifted to Applicants.

8. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isaac et al (US 5,576,364) or Bouchette (US 4,692,374). Isaac teaches the binder component being from 0.02 to 15 percent by weight of the dry web (column 7, line 60 et seq.). Bouchette teaches the binder component being from 5 to 30 percent by weight of the dry web (column 6, lines 9-11). However, such a variable would have been recognized by one skilled in the art to improve the tensile strength of the web.

Art Unit: 1771

As such, in the absence of unexpected results, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the binder having the amount instantly claimed since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

9. Claims 5, 6, 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown Reed et al (US 6,156,677). Brown Reed discloses the saturant being 70 percent by weight of the dry web (example 4). However, such a variable would have been recognized by one skilled in the art to improve the tensile strength of the web.

As such, in the absence of unexpected results, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the binder having the amount instantly claimed since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With regard to claims 14-17, Brown Reed discloses the medical packaging material having a Gurley porosity of from 1 to 45 sec/100cc (column 6, lines 38-42).

However, such a variable would have been recognized by one skilled in the art to allow a sterilant to reach the items enclosed and protected by the medical packaging material. As such, in the absence of unexpected results, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the material having the Gurley porosity instantly claimed since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the

Art Unit: 1771

optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Conclusion


10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hai Vo whose telephone number is (703) 605-4426.

The examiner can normally be reached on Tue-Fri, 8:30-6:00 and on alternating Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on (703) 308-2414. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

HV
January 15, 2003


TERREL MORRIS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700